

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: H. William BOSCH et al.

Title:

LIQUID DOSAGE COMPOSITIONS OF STABLE

NANOPARTICULATE ACTIVE AGENTS

Appl. No.:

10/619539

Filing Date: 07/16/2003

Examiner:

Unassigned

Art Unit:

1615

# INFORMATION DISCLOSURE STATEMENT **UNDER 37 CFR §1.56**

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

Submitted herewith on Form PTO/SB/08 is a listing of documents known to Applicants in order to comply with Applicants' duty of disclosure pursuant to 37 CFR §1.56. A copy of each listed document, except as noted below, is being submitted to comply with the provisions of 37 CFR §1.97 and §1.98.

The USPTO has waived the requirement under 37 CFR 1.98(a)(2)(i) to submit copies of U.S. patents and U.S. patent application publications when citing and submitting an Information Disclosure Statements in a patent application filed after June 30, 2003 and in an international application that has entered the national stage under 37 USC §371 after June 30, 2003. Accordingly, copies of these types of documents are not being supplied in connection with this application. Reference is being made to Pre-OG Notice from Office of Patent Legal Administration dated July 25, 2003, Information Disclosure Statements May Be Filed Without Copies of U.S. Patents and Published Applications in Patent Applications filed after June 30, 2003.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

### TIMING OF THE DISCLOSURE

The listed documents are being submitted in compliance with 37 CFR §1.97(b), before the mailing date of the first Office Action on the merits.

#### RELEVANCE OF EACH DOCUMENT

All documents are in English.

Documents A5, A41, A72, and A74 were cited as being relevant during the prosecution of the corresponding International application. A copy of the International Search Report is attached setting forth the portion of each document considered relevant by the examiner.

Applicants respectfully request that any listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 CFR §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

Respectfully submitted,

Michele M. Simkin

Attorney for Applicants

Registration No. 34,717

Date

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P E Substitute for form 1449B/PTO		Complete if Known		
ONFORMATION DISCLOSURE	Application Number	10/619,539		
्राध्या डेग्रेस EMENT BY APPLICANT	Filing Date	07/16/2003		
AUG 1 8 2004 SINTEMENT BY APPLICANT	First Named Inventor	H. William Bosch		
AUG .	Group Art Unit	1615		
🏃 (ဖွဲ့နှင့် as many sheets as necessary)	Examiner Name	Unassigned		
(a)se as many sheets as necessary)  1 of 2	Attorney Docket Number	029318-0961		

			U.S. PATENT DOCUMENTS							
Examiner Initials*	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of	Date of Publication of	Pages, Columns, Lines Where Relevant				
		Number	Kind Code <sup>2</sup> (if known)	Cited Document	Cited Document MM-DD-YYYY	Passages or Relevant Figures Appear				
	A1	4,783,484		VIOLANTE ET AL.	11/08/1988					
	A2	4,826,689	<u> </u>	VIOLANTO ET AL.	05/02/1989					
	A3	4,997,454		VIOLANTE ET AL.	03/05/1991					
	A4	5,145,684		LIVERSIDGE ET AL.	09/08/1992					
	A5	5,298,262		NA ET AL.	03/29/1994					
	A6	5,302,401		LIVERSIDGE ET AL.	04/12/1994					
	A7	5,318,767		LIVERSIDGE ET AL.	06/07/1994					
	A8	5,326,552		NA ET AL.	07/05/1994					
	A9	5,328,404		BACON	07/12/1994					
	A10	5,336,507		NA ET AL.	08/09/1994					
	A11	5,340,564		ILLIG ET AL.	08/23/1994					
	A12	5,346,702		NA ET AL.	09/13/1994					
	A13	5,349,957		YUDELSON	09/27/1994					
	A14	5,352,459		HOLLISTER ET AL.	10/04/1994					
	A15	5,399,363		LIVERSIDGE ET AL.	03/21/1995					
	A16	5,401,492		KELLAR ET AL.	03/28/1995					
	A17	5,429,824		JUNE	07/04/1995					
	A18	5,447,710		NA ET AL.	09/05/1995					
	A19	5,451,393		LIVERSIDGE ET AL.	09/19/1995					
	A20	5,466,440	1	RUDDY ET AL.	11/14/1995					
	A21	5,470,583		NA ET AL.	11/28/1995					
	A22	5,472,683		ILLIG	12/05/1995					
	A23	5,494,683		LIVERSIDGE ET AL.	02/27/1996					
	A24	5,500,204		OSIFO	03/19/1996					
	A25	5,510,118		BOSCH ET AL.	04/23/1996	<u> </u>				
	A26	5,518,187		BRUNO ET AL.	05/21/1996					
	A27	5,518,738	_	EICKHOFF ET AL.	05/21/1996					
	A28	5,521,218		OSIFO	05/28/1996					
	A29	5,525,328		BACON ET AL.	06/11/1996					
	A30	5,534,270		DE CASTRO	07/09/1996					
	A31	5,543,133	ļ	SWANSON ET AL.	08/06/1996					
	A32	5,552,160		LIVERSIDGE ET AL.	09/03/1996					
	A33	5,560,931		EICKHOFF ET AL.	10/01/1996	<del></del>				
	A34	5,565,188		WONG ET AL.	10/15/1996	····				
	A35	5,569,448		WONG ET AL.	10/29/1996					
	A36	5,571,536		EICKHOFF ET AL.	11/05/1996					
	A37	5,573,749		ILLIG	11/12/1996					
	A38	5,573,750		SINGH DESIENO ET AL.	11/12/1996 11/12/1996	<del></del>				
	A39	5,573,783	<del> </del>		12/03/1996					
	A40 A41	5,580,579 5,585,108		RUDDY ET AL. RUDDY ET AL.	12/03/1996					

Examiner Signature	Date Considered	

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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<sup>&</sup>lt;sup>1</sup> Unique citation designation number. <sup>2</sup>See attached Kinds of U.S. Patent Documents. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.

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	Substitute for forn	n <b>N49</b> B	/RTQ	Complete if Known			
	INFORMATION D		The same of the sa	Application Number	10/619,539		
	STATEMENT BY	<b>APPLI</b>	CANT	Filing Date	07/16/2003	_	
				First Named Inventor	H. William Bosch		
				Group Art Unit	1615		
	(use as many sheet	s as ne	cessary)	Examiner Name	Unassigned		
Sheet	2	of	2	Attorney Docket Number	029318-0961		

			U.S. PATENT DOCUMEN	ITS	
	U.S. Patent D	ocument			,
A42	5,587,143		WONG	12/24/1996	
A43	5,591,456		FRANSON ET AL.	01/07/1997	
A44	5,593,657		RUDDY ET AL.	01/14/1997	
A45	5,622,938		WONG	04/22/1997	
A46	<del></del>		LIVERSIDGE ET AL.	05/13/1997	
A47	5,643,552		ILLIG	07/01/1997	
A48	5,662,883		BAGCHI ET AL.	09/02/1997	
A49			BAGCHI ET AL.	09/09/1997	
A50	5,718,388		CZEKAI ET AL.	02/17/1998	
A51	5,718,919		RUDDY ET AL.	02/17/1998	
A52	5,741,522		VIOLANTE ET AL.	04/21/1998	
A53			WIEDMANN ET AL.	05/05/1998	
A54	5,776,496		VIOLANTE ET AL.	07/07/1998	
A55			DE GARAVILLA ET AL.	11/10/1998	
A56			CZEKAI ET AL.	01/26/1999	
A57			LIVERSIDGE ET AL.	04/04/2000	
A58			LIVERSIDGE ET AL.	05/30/2000	
A59	6,153,225		LEE ET AL.	11/28/2000	
A60	6,165,506		JAIN ET AL.	12/26/2000	
A61	6,221,400	B1	LIVERSIDGE ET AL.	04/24/2001	
A62	6,264,922	B1	WOOD ET AL.	07/24/2001	
A63	6,267,989	B1	LIVERSIDGE ET AL.	07/31/2001	
A64	6,270,806	B1	LIVERSIDGE ET AL.	08/07/2001	
A65	6,316,029	B1	JAIN ET AL.	11/13/2001	
A66	6,375,986	B1	RYDE ET AL.	04/23/2002	
A67	6,428,814	B1	BOSCH	08/06/2002	
A68		B1	REED ET AL.	08/13/2002	
A69	6,432,381	B1	LIVERSIDGE ET AL.	08/13/2002	
A70	<del></del>	B2	RYDE ET AL.	07/15/2003	
A71	2002/0012675	A1	JAIN ET AL.	01/31/2002	

#### **FOREIGN PATENT DOCUMENTS**

		Foreign Patent Document				Date of Publication of Cited Document	Pages, Columns, Lines, Where	
Examiner Initials*	Cite No. <sup>1</sup>	Office	<sup>3</sup> Number⁴	Kind Code <sup>5</sup> (if known)	Name of Patentee or Applicant of Cited Documents	MM-DD-YYYY	Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
	A72	WO	96/24335	A1	NANOSYSTEMS LLC	08/15/1996		
	A73	wo	02/098565	A1	ELAN PHARMA INC.	12/12/2002		
	A74	EP	0 601 619	A2	STERLING WINTHROP	06/15/1994		

- Indiana		
Examiner	Date	
Signature	Considered	

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